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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,682	03/02/2004	Robert G. Schinazi	RSZ-4	2590
22827	7590	06/13/2007		
DORITY & MANNING, P.A. POST OFFICE BOX 1449 GREENVILLE, SC 29602-1449			EXAMINER STIGELL, THEODORE J	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 06/13/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/791,682

Applicant(s)

SCHINAZI ET AL.

Examiner

Theodore J. Stigell

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,16,19,20,23-25 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-15,17,18,21,22 and 26-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Response to Amendment***

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 6-15, 17-18, 21-22, and 26-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Binks (2,878,836). Binks discloses a medical apparatus flow restrictor comprising a housing (10) having an inlet (11) and an outlet (34), and a fluid path defined through the housing between the inlet and outlet, at least one pair of opposed restriction devices (14,16) seated within the housing between the inlet and outlet, the restriction devices comprising opposing planar surfaces in contact with each other, the restriction device disposed within the flow path such that fluid delivered to the inlet passes through the opposing surfaces prior to flowing from the outlet, wherein the opposing surfaces have a random surface roughness and opposed surface area defining a random flow field between the opposed surfaces, the degree of random surface roughness and surface area of the random flow field defined as a function of a desired flow rate through the restrictor (the Examiner is not giving much patentable

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weight to this limitation due to the Applicant's admission in the Specification that the surface roughness is inherent to the material used, the surface roughness might not be discernible to the unaided eye, that the surface roughness may be determined through routine experimentation, and that the surface roughness can be achieved by using conventional processes well-known in the art, see page 5, lines 5-10 and page 12), and wherein the random flow field is defined by a random pattern of protrusions between the opposing surfaces and defines the sole regulated restrictive flow path through the restrictor for delivering a desired flow rate, wherein a flow path is defined within the housing such that the fluid flows to a perimeter (21) of the flat planar members and migrates radially inward between the opposing surfaces to opening (28), wherein the restriction devices are formed of a compressible material that fluid flow between the opposing surfaces is varied by varying a compressive pressure applied to the restriction devices, wherein the housing is formed of two parts and can be permanently or separately attached, and further comprising a seal (not numbered) in the housing.

Claims 1-3, 7-15, 17, 18, 21, 22, and 26-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Utracki et al (US 6,550,956). Utracki discloses a flow mixer/regulator having a housing 10 with an inlet (12a, 14a), and an outlet 19, at least one pair of opposed restriction devices (18,30,32) with opposing surfaces (20', 32'), a seal (18, 18a). At least one of the restriction devices includes an orifice 20a. The flow mixer can control flow by adjusting the gap between the restriction devices (col. 7). The Examiner is giving much patentable weight to the random surface roughness limitation

for the same reasons stated above. The Examiner also argues that all surfaces have a random surface roughness when seen at the microscopic level.

Claims 1-3, 6-15, 17-18, 21-22, and 26-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Bierman et al. (3,868,973). Bierman discloses a medical apparatus flow restrictor comprising a housing (10) having an inlet (22) and an outlet (24), and a fluid path defined through the housing between the inlet and outlet, at least one pair of opposed restriction devices (14) seated within the housing between the inlet and outlet, the restriction devices comprising opposing planar surfaces in contact with each other through (16), the restriction device disposed within the flow path such that fluid delivered to the inlet passes through the opposing surfaces prior to flowing from the outlet, wherein the opposing surfaces have a random surface roughness and opposed surface area defining a random flow field between the opposed surfaces, the degree of random surface roughness and surface area of the random flow field defined as a function of a desired flow rate through the restrictor, and wherein the random flow field is defined by a random pattern of protrusions between the opposing surfaces and defines the sole regulated restrictive flow path through the restrictor for delivering a desired flow rate, wherein a flow path is defined within the housing such that the fluid flows to a perimeter of the flat planar members and migrates radially inward between the opposing surfaces to opening, wherein the restriction devices are formed of a compressible material that fluid flow between the opposing surfaces is varied by varying a compressive pressure applied to the restriction devices, wherein the housing is

formed of two parts and can be permanently or separately attached, and further comprising a seal (16) in the housing.

### ***Response to Arguments***

Applicant's arguments filed 3/28/2007 have been fully considered but they are not persuasive.

In response to the Applicant's arguments that Binks and Utracki do not anticipate the claimed invention, the Examiner respectfully disagrees. Binks and Utracki disclose devices for delivering fluid at a desired flow rate with opposing surfaces defining the flow field. The surfaces have random fields of voids, spaces, protrusions, etc. at the microscopic level. The flow rate is inherently affected by the surface of the opposing surfaces. Therefore, if a device delivers a fluid at a desired flow rate, the surface of the device (part of the device in touch with the fluid) inherently affects the flow rate and is responsible for the desired flow rate.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the


shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Theodore J. Stigell

  
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